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Docket 50709-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Applicant:	SEMENIUK, Lisa	Group Art Unit: 3743
Serial No.:	10/707,210	Examiner: Nihir Patel
Filed:	November 26, 2003	
For:	"METHOD AND APPARATUS FOR PREVENTING EAR ABRASION"	

Declaration Under 37 CFR Sec. 1.132

Province of Alberta
CANADA

I, Lisa Semeniuk, of the City of Calgary, Province of Alberta, Canada, hereby declare as follows:

I am the inventor of the above noted patent application.

BACKGROUND INFORMATION

I developed the method of preventing ear abrasion and oxygen mask/strap combination claimed in this patent application to solve a problem of ear abrasion that I, as a medical health care professional, had observed was a common problem with persons who wear oxygen masks for a long time, for example patients in chronic care or in intensive care.

Ear abrasion occurs because the single strap that is used to hold the oxygen mask, which is quite tightly applied around a person's head, tends to slip down and rest on the person's ear, where it rubs repeatedly against the same part of the ear. While health care professionals and persons wearing the oxygen masks try to keep the strap in its proper place, it continually slips down and there is nothing that can be done except to re-position the strap.

I am enclosing pictures showing the problem of ear abrasion in Appendix A. These are pictures of one of many patients who suffer from ear abrasions. As you can see, the problem is real and it needs a solution. It should be quite apparent that these ear abrasions are not only painful and uncomfortable, but they can lead to infection if not treated.

LONG FELT NEED

People in the health care industry have tried to deal with the ear abrasion problem in a number of ways, for example by applying Duoderm, which is a thin layer of dressing, to the affected area, or by applying Vaseline, or by keeping the strap away from the affected area. However, none of these methods result in a satisfactory resolution of the problem. There has been a long-felt need in the industry to deal with this problem, but no one has come up with a satisfactory solution.

I have a scientific (B.Sc. Honours Physiology, M.Sc. Cardiovascular Physiology, Ph.D. Medical Science, Post-doctoral research fellowship Medicine) and clinical (Registered Nursing) background. My evidence is therefore based on personal experience and knowledge that others have shared that experience.

During my studies and training and in my experience, I have not encountered any information that would suggest to any person working in the area of patient care, that they could solve the problem of ear abrasion by designing a different strap to use with conventional oxygen masks used in hospitals. I have seen nothing that would suggest that something, other than the single strap that is universally used in the health care industry, might be used to hold an oxygen mask to a person's head. In fact, the stigma against changing the strap is so strong that health care professionals have learned to deal with this problem only reactively (by applying Duoderm and Vaseline), rather than proactively, to prevent the problem altogether. There is simply no effective, relatively inexpensive and convenient method that can be used to prevent ear abrasion in persons who wear oxygen masks.

My patent agent has kept me advised of what has been happening with my US patent application. I am aware that the examiner in the US patent office is taking the position that a respirator and an oxygen mask used in hospitals are the same thing. I disagree with that. A respirator and an oxygen mask have a different function. A respirator is an apparatus worn over the face to prevent the breathing in of dust, smoke, or other harmful substances, or an apparatus used to provide artificial respiration. An oxygen mask is designed to simply supply oxygen to a wearer. Although a respirator may be adapted to accommodate an oxygen source, it is still a respirator, and not an oxygen mask.

SKEPTICISM OF EXPERTS

I demonstrated to those in the health care industry, and these are people who are skilled and knowledgeable in this area, that my strap would actually work to satisfactorily hold an oxygen mask to a person's head and to deliver oxygen to that person. There was a concern that an oxygen mask, when used with my strap, might not deliver the required oxygen to a patient- *i.e.,* that it might flip over or not have a good seal.

My patent agent has shown me the patent to Norfleet (U.S. patent no. 6,418,929) and I note that the patent actually discusses exactly this point, about flipping over. Norfleet states that a problem encountered with the use of the single strap to hold the face mask against the face of a wearer is that the face mask can be easily pivoted about the axis defined by the two points where the strap is attached to the face mask. This problem would be perceived to be even greater if the strap was elevated even higher on the head, which my strap does. In fact, Norfleet developed an oxygen mask and strap assembly that connected at two points on each side of the mask to avoid the problem that they thought would exist, but which I have shown does not.

In addition to demonstrating efficacy, it was also important to demonstrate that the strap was more comfortable than standard therapy through research, since there is emphasis

in medicine on evidenced based practice. A Clinical Trial with my new strap with a conventional oxygen mask was instrumental in addressing these two issues, and is provided in Appendix B. I am enclosing a copy of an application to perform a Clinical Trial of my strap (that was filed along with Dr. T. Anderson), which was submitted to the Calgary Health Region. This application was filed with the Adult Research Committee of the Calgary Health Region, and the purpose of this Clinical Trial was to demonstrate the efficacy and comfort of the strap (the "COMFO_2-STRAP") that I invented- *i.e.*, to show that it actually works to deliver oxygen and its comfortable, and of course, avoids ear abrasion. One objective of the study is described on page 3, as "to study the effectiveness of the experimental strap in maintaining oxygen saturation in patients on oxygen mask therapy". To this end, oxygen saturation levels were measured on a regular basis, to ensure that the oxygen mask remained in position. Therefore, before this study was done, it was not clear that this strap would be useable in a clinical setting. I think that if a Regional Health Authority allows me to conduct a Clinical Trial addressing efficacy, that this is good evidence that my invention was not "obvious". In fact, the allowance of a clinical trial by a review panel of health care practitioners is evidence that there were some people of skill in the art who suspected that it might not work, and it may help to explain why no one has done this before.

COMMERCIAL SUCCESS

I have discussed and shown my strap, which embodies the invention claimed, to many people in the health care industry. Many have tried it and liked it, and would like to have access to the product. Many others have inquired about the availability of my product. I know that if and when I get this product up and running, that there will be a large market for it as there is an extreme interest for this product. Completion of the clinical trial required the signatures of the patient care managers from all the units that would participate in the study. Every manager approached for signatures was very aware of the problem and very interested that there may be a potential solution. Respiratory

technicians who were aware of the trial and were impressed with the device throughout the trial continue to ask when the device will be available.

Attached as Schedules C and D, are letters written by Dr. MacRae and Mr. Will Cunnington, which attest to the need for a means of preventing ear abrasion and the lack of effective alternatives. The letters attest to the real and urgent need for a product like the subject matter of my patent application. Mr. Cunnington is the director of respiratory therapy and Dr. MacRae is a clinical doctor and assistant professor at a large teaching hospital (Foothills Hospital, Calgary, Alberta, Canada). Both individuals have encountered problem ear abrasions in patients on numerous occasions.

I have done pricing research and know that I can make and sell this product at a competitive price that will induce users in the health care industry to buy it. I have little doubt that I will experience significant demand for my product once I put it onto the marketplace.

I have approached potential licensees and investors, who have expressed an interest in working with me to develop this project, but they are hesitant to do so absent patent protection. This is understandable, as my invention would be easy to make and copy. I have no doubt that others will copy it if there is no patent protection, because I have every reason to believe it will be very successful.

Attached as Schedule E is a letter written by University Technologies Incorporated (UTI) which evidences the fact that, if I were to obtain patent protection for this invention, that they would likely invest in the commercial development of the product. I have blacked out a portion of the letter that deals with patenting strategy, and is irrelevant to the issue for which I am submitting the letter.

In my opinion, commercial success will quickly follow obtaining patent protection, as I will then have the financial resources to make and sell the product.

I make this Declaration in support of the patent application noted above.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DECLARED this 15th day of March, 2006 at the City of Calgary, Province of Alberta, Canada.

Lisa Semeniuk

Exhibit A
of the Declaration under 37 CFR Section 1.132
by Lisa Semeniuk

Left ear abrasion.

Right ear - Futile efforts by nursing staff to relieve patient discomfort. A piece of duoderm was applied to the affected area.

Exhibit B
of the Declaration under 37 CFR Section 1.132
by Lisa Semeniuk

Foothills Medical Centre
1403 29 Street NW
Calgary, Alberta, Canada T2N 2T9
website www.calgaryhealthregion.ca

calgary health region
Foothills Medical Centre

11 March 2002

Dr. Todd Anderson
Department of Cardiac Sciences
Foothills Medical Centre

Dear Dr. Anderson:

Re: #16354 - Efficacy and Comfort of the Comfo2-Strap

Thank you for submitting an application regarding the above project for review by the Adult Research Committee of the Calgary Health Region (CHR). This will confirm that the committee has granted institutional approval for this project, and that the CHR has granted approval under Sections 53 and 54 of the Health Information Act. **This approval is contingent on approval by the Conjoint Health Research Ethics Board.**

It is understood from your submission that your study will be entirely funded through external sources and that the CHR will be reimbursed for all research costs associated with this project. To facilitate a smooth startup of your project, please notify affected departments in the Region well in advance of your intent to initiate this study.

Please note that it is a requirement that you communicate in writing the study results to the CHR Adult Research Committee, and provide any copies of publications arising from the research as well as provide feedback regarding any problems encountered during the course of the study.

Please accept the committee's best wishes for success in your research.

Yours sincerely,

Thomas E Feasby, MD, FRCPC
Chair, Adult Research Committee

cc: Dr. L Semeniuk, Dr. LB Mitchell, Conjoint Health Research Ethics Board

UNIVERSITY OF CALGARY

FACULTY OF MEDICINE

Office of Medical Bioethics
Heritage Medical Research Building/Rm 93
Telephone: (403) 220-7990
Fax: (403) 283-8524

2002-03-07

Dr. T.J. Anderson
Division of Cardiology
Foothills Hospital
Calgary, Alberta.

Dear Dr. Anderson:

Re: Efficacy and Comfort of the Comfo2-Strap

GRANT ID: 16354

The above-named research project and the consent form have been granted ethical approval by the Conjoint Health Research Ethics Board of the Faculties of Medicine, Nursing and Kinesiology, University of Calgary, and the Affiliated Teaching Institutions. The Board conforms to the Tri-Council Guidelines, ICH Guidelines and amendments to regulations of the Food and Drug Act re clinical trials, including membership and requirements for a quorum.

The study meets the requirements of the Health Information Act.

You and your co-investigators are not members of the CHREB and did not participate in review or voting on this study.

Please note that this approval is subject to the following conditions:

(1) you must obtain approval from your appropriate institution where the research project will be conducted (if applicable);
(2) a copy of the informed consent form must have been given to each research subject, if required for this study;
(3) a Progress Report must be submitted in one year, 2003-03-07, containing the following information:
    (i) the number of subjects recruited;
    (ii) a description of any protocol modification;
    (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
    (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
    (v) a copy of the current informed consent form;
    (vi) the expected date of termination of this project;
(4) a Final Report must be submitted at the termination of the project.

Please accept the Board's best wishes for success in your research.

Yours sincerely,

Christopher J. Doig, MD, MSc, FRCPC
Chair, Conjoint Health Research Ethics Board

c.c. Adult Research Committee. Dr. D. Megran (information)

APPLICATION FOR SCIENTIFIC, ADMINISTRATIVE & ETHICAL REVIEW OF CLINICAL TRIALS/HEALTH RESEARCH university of calgary | calgary health region

SECTION A: GENERAL INFORMATION

DATE RECEIVED BY: CAH/CHRO/OMB _____ GRANT ID # _____

1. PROTOCOL TITLE:
Efficacy and Comfort of the Comfo2-strap

2. LOCAL PRINCIPAL INVESTIGATOR: Dr. T. Anderson M.D.
(Note: students, residents & fellow cannot be listed as PI)
FACULTY (specify rank) and/or DEPARTMENT: Associate Professor, Medicine
PHONE: 670-1020 FAX: 670-1592 E-MAIL: todd.anderson@calgaryhealthregion.ca
CO-INVESTIGATOR(s): Dr. L. Semeniuk PhD
*(indicate student, resident, fellow with an *)*

Research Coordinator/Assistant(s): L. Semeniuk
Phone: 220-4538 Fax: 220-8102 E-Mail: lsemeniu@ucalgary.ca

******PLEASE CHECK THE FOLLOWING IF APPROPRIATE******

☐ Masters/PhD Project ☐ Medical Student Project ☐ Undergraduate Project ☐ Resident or Fellow Project

3. ANTICPATED START DATE: April 1, 2002
ANTICIPATED COMPLETION DATE: June 1, 2002
ANTICIPATED NUMBER OF SUBJECTS (Local only): 26

4. TYPE OF RESEARCH: ☒ Clinical Trial ☐ Health Research ☐ Basic Science

5. LOCATION OF RESEARCH: *check all that apply*

Calgary Health Region

☒ FMC	☐ ACH	☐ Care in the Community
☐ PLC	☐ SAC	☐ Healthy Communities
☐ RVH	☐ CBH	☐ Other:

University of Calgary and other Sites

☐ UCMC	☐ Faculty of Kinesiology	☐ TBCC
☐ HMRC	☐ Faculty of Nursing	☐ Off-site Medical Office
☐ CHS	☐ Other: (Specify)	

6. PROPRIETARY RIGHTS: *Please check one*
☒ The investigators can alter the protocol according to their judgment and have full rights to information derived from this research and publication of this information.
☐ This research is being done for a sponsor who controls the details of the protocol and the rights to the information gathered.

7. ***This serves as application for disclosure of health information to be used in research and I agree as follows:***
(A copy of the Health Information Act is available at www.ucalgary.ca/md/cah/research)

a) to comply with the *Health Information Act* and all regulations under that Act [section 54(1)(a)(i)];
b) to comply with all conditions imposed by the CHR and the University of Calgary relating to the use, protection, disclosure, return or disposal of the health information [section 54(1)(a)(ii)];
c) to comply with all requirements of the CHR and the University of Calgary to provide safeguards, against the identification, direct, or indirect, of an individual who is the subject of the health information [section 54(1)(a)(iii)];
d) to use the health information only for the purpose of conducting the proposed research [section 54(1)(b)];
e) to not publish the health information in a form that could enable the identity of the subject of the health information [section 54(c)];
f) to not attempt to contact the subject of the health information except in accordance with the Act [section 54(d) and 55];
g) to allow the Custodian of health information access as prescribed by the Act [section 54(e)].

_____

APPLICATION FOR SCIENTIFIC , ADMINISTRATIVE & ETHICAL REVIEW OF CLINICAL TRIALS/HEALTH RESEARCH

UNIVERSITY OF CALGARY calgary health region

SECTION B - DEPARTMENT APPROVALS

Please obtain your Department Head's signature and signatures of all departments/divisions/services whose operations will be affected by your protocol. This is to ensure that prior to commencement of the investigation, these individuals have had an opportunity to assess the impact of the proposal on their area. This will include reviewing the proposed budget so they can accommodate any additional requirements arising from the protocol.

TITLE OF PROPOSED RESEARCH: Efficacy and Comfort of the Comfo2-strap

My signature below acknowledges and accepts the impact (clinical, financial or otherwise) of this research study on my department/division/program/portfolio and I agree with the costs itemized in the study budget

Signature of Department Head/Administrative Officer	L. Brent Mitchell (Print Name)	Feb 15, 02 (Date)

	Department/Service	Print Name	Signature	Date
☐ Yes ☒ No	Anesthesia			
☐ Yes ☒ No	Cardiac Diagnostics			
☐ Yes ☒ No	Health Information Services/QIHI			
☐ Yes ☒ No	Diagnostic Imaging			
☐ Yes ☒ No	Health Records			
☐ Yes ☒ No	HMRC			
☐ Yes ☒ No	ICU			
☐ Yes ☒ No	Lab Med & Pathology			
☐ Yes ☒ No	Neurodiagnostics			
☒ Yes ☐ No	Nursing Unit			
☒ Yes ☐ No	Nursing Unit			
☒ Yes ☐ No	Nursing Unit			
☐ Yes ☒ No	Nutritional Services			
☐ Yes ☒ No	Outpatient Services			
☐ Yes ☒ No	Pharmacy			
☒ Yes ☐ No	Respiratory Therapy			
☐ Yes ☒ No	Surgical Services			
☐ Yes ☒ No	Other:			
☐ Yes ☒ No	Other:			
☐ Yes ☒ No	Other:			
☐ Yes ☒ No	Other:			

APPLICATION FOR SCIENTIFIC , ADMINISTRATIVE & ETHICAL REVIEW OF CLINICAL TRIALS/HEALTH RESEARCH

UNIVERSITY OF CALGARY calgary health region

SECTION C - RESEARCH PROTOCOL SUMMARY

The purpose of this section is to outline the scientific structure of your study. Point form is acceptable. All sections must be complete (do not simply refer to sections in your proposal).

1. List a minimum of 3 key words which describe your study (MeSH recommended). Please include keywords that would be interpretable by a non-medical audience

For example: (1) Cardiology (2) hypertension (3) myocardial infarction

(1) human
(2) adult
(3) comfort assessment
(4) oxygen mask strap
(5)
(6)

2. Does your study involve any of the following (check all that apply)?

☒ Questionnaire ☐ Interview ☐ Chart Review ☐ Database Linkage

Has this study received approval from an ethics committee in Alberta? ☐ Yes ☒ No

3. Hypothesis/Research Question/Objectives:

Specific objectives of this study are:

1. To study the effectiveness of the experimental strap in maintaining oxygen saturation in patients on oxygen mask therapy.

2. To assess whether comfortable mask placement is achieved with the experimental strap.

4. Rationale and Significance:

Existing oxygen mask straps secure the mask at an angle that results in ear abrasions and discomfort for the patient. Frequent readjustment of the mask and strap is essential to establish proper, comfortable mask placement and subsequent medical therapy. This problem has not previously been addressed. The Comfo2-strap is angled so that a more secure position of the mask is obtained without contacting patient ears. Use of this device may result in an improved quality of life for the patient if proven to be effective and comfortable in this controlled, randomized, blinded clinical trial.

5. Basic Study Design (Briefly describe your study, continued on next page):

Efficacy will be assessed using an interventional method. Control oxygen levels will be monitored every 5 minutes for 30 minutes using a finger probe oxygen saturation measuring device to confirm stable oxygen saturation levels. The existing oxygen mask strap will be replaced with the control (same strap n=13) or Comfo2-strap (n=13) after ensuring that oxygen saturations decrease by 5%. Oxygen levels will be assessed every 5 minutes for another 30 minutes to confirm stable oxygen saturation levels using the experimental device.

Comfort level assessment will be descriptive in the form of a patient comfort level scale (Appendix 4) to be completed before the experimental strap is trialed. This will assess comfort level of the existing oxygen mask strap. Patient's will be asked to complete the same comfort level assessment 24 hours after the existing strap is replaced with the experimental strap. Patients will be asked to continue the use of the experimental strap until oxygen therapy is discontinued as part of there regular medical treatment or until the 3 day end point of the study. This will allow nursing staff to comment on the security of mask position on a sheet of paper that will be left by the patient's bedside for the duration of the study.

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5. Br[redacted] Study Design (continued):

6. Methods:

a) Subject Numbers: How many local subjects? 26 How many total subjects? 26

b) Major Inclusion/Exclusion Criteria:

Inclusion criteria: The subjects will be patients who have been on oxygen mask therapy for a minimum of 24 hours so that they can adequately assess comfort of the existing straps. The patients must be alert and oriented, and capable of completing a comfort level assessment.

Exclusion criteria: Patient refuses to give informed consent. Concomitant severe medical problem preventing participation.

c) Interventions (What will be done to the subjects and for how long?)

Oxygen saturation levels will be monitored with a finger probe device every 5 minutes for a total of 60 minutes. Existing oxygen mask straps will be replaced with the experimental strap (control or Comfo2-strap). Patient's will wear the experimental strap until their oxygen mask therapy is discontinued or until the 3 day study endpoint.

In some patient's, photographs of only the ear abrasions will be taken for illustative purposes for publication.

d) Primary Outcome Variables (What will be measured?)

Oxygen saturation levels will be measured using a noninvasive finger probe device. Comfort level will be assessed using a visual analogue scale (Appendix 4).

e) Data Collection (How will data be collected/What instruments will be used?)

Data will be collected using a noninvasive standard finger probe device obtained from respiratory services. The comfort level scale (visual analogue scale) being used has previously been developed and validated in other studies for comfort level assessment (Appendix 4).

7. Data Analysis:

a) What is your sample size and how do you justify it? (Provide details of sample size calculation).

The sample size estimates were based on the primary hypothesis: There will not be a difference in oxygen saturation levels before and after the experimental strap is adapted to the oxygen mask. Null hypothesis: There will be no difference. Estimations: m1=90, m2=95. Sigma=5. To achieve a 91% power to detect a 5% difference in the mean oxygen saturation levels, with an alpha of 0.05 using a two-sided test, we estimate that 13 subjects will be required in the experimental group (computer output from PASS). The control group (n=13) is important to evaluate for the placebo effect and test reliability in comfort level assessment.

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b) Data Analysis (Which method of analysis will you use?)

Mean baseline oxygen saturation values will be compared with the values obtained after application of the experimental device by Student's paired t test. Satistical significance will be accepted at the 95% confidence level ($p<0.05$).

Wilcoxon rank sum test will be used to compare comfort level assessment scores.

8. Recruitment:

a) How will you identify potential subjects?

The study nurse will canvass patients on oxygen mask therapy by asking the patient's primary nurses or the head nurses on the specified units.

b) Who will recruit the potential subjects?

The study research nurse with active AARN registration and CHR affiliation will approach patients, explain the nature of the study and obtain informed consent.

c) Where will you recruit potential subjects?

Only the CHR Foothills Hospital site will be used to recruit potential subjects. Only the units for which the Medical Director and Unit Manager consents have been obtained (Appendix 2) will be used for recruitment.

d) What method (s) will you use to recruit potential subjects?

The study nurse will canvass for patients by visiting the units.

e) Have you included a copy of your recruitment poster/ad in this application?
☐ Yes, included ☐ No ☒ N/A

f) Would you like to place a recruitment posting for this study on the UofC website for public access? ☐ Yes ☒ No

SECTION F - BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR

☒ A recent CV (within 3 years of the date of this application) is on file at Centre for Advancement of Health, Child Health Research Office, or the Office of Medical Bioethics.

OR

☐ I have included one copy of my CV with this application.

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SECTION E – BUDGET SUMMARY

There has been considerable concern expressed in the lay and medical press on payment to researchers for clinical trials. To ensure that the University of Calgary is able to meet all regulatory requirements, full budget details are essential. If your study is receiving funding from industry or a granting agency, you must attach the budget submitted to or received from that external source as well as complete this page.

1. Human Resources (List all support personnel to be engaged in this study)

POSITION	SALARY	BENEFITS	HRS/WK	TOTAL HRS	COST
					$
					$
					$
					$
					$
				Subtotal (1)	$

2. Services/Procedures (List x-rays ECGs, etc)

#Usual Care	Research Specific\$ per item		Total
oxygen sats	x $	=	$
	x $	=	$
	x $	=	$
	x $	=	$
	x $	=	$
	x $	=	$
	x $	=	$

Report tests which are usual care but do not include costs for these tests in your calculations Subtotal (2) $

3. Supplies and Equipment (List all supply and equipment requirements)
oxygen saturation device will be supplied by the respiratory services department for the duration of the study.
Comfo2-strap is being donated by Limark Medical (Comf02-strap).

Subtotal (3) $

4. Other Services:

Subtotal (4) $

Total All Services Above (1-4) $

Industry Sponsored Clinical Trials Overhead (*25%: applied to amount received*): $
Industry Sponsored Clinical Trials ERB Review Fee:$

TOTAL COST (including overhead if applicable) $

FUNDING SOURCE(s): Complete *sections A, B, and C as applicable*

A. Non-Industry Sponsored Funding: list sources

	Amount:	Status:
	$	☐ Applied ☐ Received
	$	☐ Applied ☐ Received
	$	☐ Applied ☐ Received

☐ Granting Agency ☐ Internal (PI or Dept) ☐ No Cost ☒ Fees Waived ☐ Other:

B. Industry Sponsored Clinical Trial: ☐ grant or ☐ contract
Company Name: Amount per patient: $
1. Is overhead included in the amount per patient reported above? ☐ Yes ☐ No ☐ Not applicable
2. Will the Local Investigator or department receive additional funds for participating in this trial? ☐ Yes ☐ No

C. Industry or Grant Funding Source:
Please attach the original budget submitted to or received from the external funding source.

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SECTION F – PRIVACY PROTECTION

This section MUST be completed for all research studies. The *Health Information Act* requires an assessment of the risk to privacy. Please describe this below. Also describe how you will reduce the risk to privacy (see examples on page 8). A copy of the *Health Information Act*, is available at www.ucalgary.ca/md/cah/research.

Project Privacy Management Issues

Please provide a response/details regarding all of these issues:

1. All personal information sources and major data elements.
CHR Foothills Hospital. Length of oxygen mask therapy will be obtained from reviewing the patient's chart.

2. Purpose for collection and use of data.
The data collected will be used for publication in a peer reviewed journal.

3. Project personnel who have access to the information.
Principal investigator:Todd Anderson; and Co-investigator/study nurse Lisa Semeniuk

4. Whether any of the information will be disclosed to anyone other than project personnel; or for any purpose other than the purpose included in this application.
N/A

5. Will you seek individual consent for access to patient information? Yes ☒ No ☐

If yes, this should be incorporated in the consent form included with the application. If no, please indicate the reason for not seeking individual consent. You may wish to refer to the HIA for guidance, but some of the reasons might include: you are a clinician in charge of care of the patient, you have administrative authority over the clinical areas, or that it is impractical or unreasonable to obtain consent.

6. The storage and final disposition of the information.
Information will be stored on paper in 1 study binder. Data analysis will be stored on a 3.5 computer disk. These items will be kept in a box in the locked research office of the principal investigator for a period of 7 years and then be destroyed.

7. Who has access to the information abstracted?
The information abstracted will be available to the public and will be publicized in a peer reviewed journal.

8. Who has access to the listing of names and study ID numbers, if there is a study ID number?
Principal investigator:Todd Anderson; and Co-investigator/study nurse Lisa Semeniuk

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Privacy Risk and Controls Assessment

Please provide an assessment of the privacy risks and controls used to mitigate these risks for project, including the following examples:

Risk	*Mitigation Measures*
Unauthorized external or internal access to identifying information through: - Active use - Transmission - Storage - Disposal	- project personnel screening/agreements - access authorization procedures - designated systems administrator - passwords/screen timeouts - system access audits/disclosure logs - secure mail/transport - firewall/virus protect - encrypted transmission - secure paper-based storage - shredding/wiping
Identification through publication or release.	- Aggregations levels - Alternate identifers
Identification through data-matching	Use of non-linkable elements or identifiers
Loss of data control outside jurisdiction	Confidentiality and security agreements for out-of-province recipients or storage providers
Loss of data control through non custodian contractors	Confidentiality and security agreements (e.g., information managers, ASPs)

Comments:
One computer file labelled with an undistinguishing file name stored in Dr. Anderson's research office will contain only the patient name, hospital number and a study ID number. All data and information will subsequently be stored and analyzed on the computer according to their respective ID number in different files. Any paper information will be shredded at the University of Calgary or stored in Dr. Andersons locked research office. Only Dr. Anderson and Dr. Semeniuk will have access to the identity of the patients.

APPENDIX 1

FULL STUDY PROTOCOL

FULL STUDY PROTOCOL

RATIONALE AND SIGNIFICANCE

Existing oxygen mask straps secure the mask at an angle that results in ear abrasions and discomfort for the patient. Frequent readjustment of the mask and strap is essential to establish proper, comfortable mask placement and subsequent medical therapy. This problem has not previously been addressed. The Comfo2-strap is angled so that a more secure position of the mask is obtained without contacting patient ears. Use of this device may result in an improved quality of life for the patient if proven to be effective and comfortable in this controlled, randomized, blinded clinical trial.

OBJECTIVES

Specific objectives of this study are:

1. To study the effectiveness of the experimental strap in maintaining oxygen saturation in patients on oxygen mask therapy.

2. To assess whether comfortable mask placement is achieved with the experimental strap.

RESEARCH METHODS

I Study Design

This will be a prospective randomized, blinded study with 26 patients (13 control, 13 experimental). To study the efficacy of the experimental strap, an equivalence test will be used in an interventional study to determine whether there is any change in oxygen

saturation of the patient with the experimental device. A descriptive method using a visual analogue comfort level scale will be used to study patient comfort. The efficacy will be determined immediately. The length of the study will be 3 days unless oxygen therapy is discontinued earlier as part of the regular care. A 24 hour minimum will be used as a variable to exclude a patient. This length was chosen in order to assess comfort adequately.

II Subjects

Inclusion Criteria

The subjects will be patients who have been on oxygen mask therapy for a minimum of 24 hours so that they can adequately assess comfort of the existing straps. The patients must be alert and oriented, and capable of answering a questionnaire.

Exclusion Criteria

Patient refuses to give informed consent. Concomitant severe medical problem preventing participation.

Recruitment

The study nurse will canvass patients on oxygen mask therapy by asking the patient's primary nurses or the head nurses on the specified units. Consent to recruit patients on the specified units has been obtained by the Medical Directors and Unit Managers (Appendix 2). Consent has also been obtained by the Respiratory Services Director (Appendix 2).

The study research nurse with active AARN registration and CHR affiliation will approach patients, explain the nature of the study and obtain informed consent (Appendix 3).

Study Group Allocation

Thirteen control subjects (13) and thirteen (13) Comfo2strap subjects will be allocated in a randomized fashion to their respective groups. Identical envelopes will conceal the group allocation. Once informed consent is obtained, the researcher will randomly select an envelope for that patient. The device will unbiasly be referred to as the experimental strap regardless of the group allocation.

III Protocol

Efficacy will be assessed using an interventional method. Control oxygen levels will be monitored every 5 minutes for 30 minutes using a finger probe oxygen saturation measuring device to confirm stable oxygen saturation levels. The existing oxygen mask strap will be replaced with the control (same strap) or Comfo2-strap after ensuring that oxygen saturations decrease by 5%. Oxygen levels will be assessed every 5 minutes for another 30 minutes to confirm stable oxygen saturation levels using the experimental device.

Comfort level assessment will be descriptive in the form of a patient visual analogue comfort level scale (Appendix 4) to be completed before the experimental strap is trialed. This will assess comfort level of the existing oxygen mask strap. Patient's will be asked

to answer the same comfort level assessment 24 hours after the existing strap is replaced with the experimental strap. Patients will be asked to continue the use of the experimental strap until oxygen therapy is discontinued as part of there regular medical treatment or until the 3 day end point of the study. This will allow nursing staff to comment on the security of mask position on a sheet of paper that will be left by the patient's bedside for the duration of the study.

Study end points

The experiment will be terminated:

i) At the end of the 3 day study period unless terminated earlier as part of the regular oxygen therapy. 24 hours is the minimum required time to assess adequately for comfort.
ii) If the oxygen saturation levels decrease by > that 5% when the experimental strap is applied.
iii) Initial instability with the existing strap occurs defined as oxygen saturation fluctuations of 5% occur.
iv) If an initial decrease in oxygen saturations of 5% does not occur so the efficacy of the experimental strap can be assessed.
v) Untowards effects occur as a result of the Comfo$_2$-strap.

IV Statistical Considerations

The sample size estimates were based on the primary hypothesis: There will not be a difference in oxygen saturation levels before and after the experimental strap is adapted to the oxygen mask. Null hypothesis: There will be no difference. Estimations: m1=90, m2=95. Sigma=5. To achieve a 91% power to detect a 5% difference in the mean oxygen saturation levels, with an alpha of 0.05 using a two-sided test, we estimate that 13 subjects will be required in the experimental group (computer output from PASS). The

control group (n=13) is important to evaluate for the placebo effect and test reliability in comfort level assessment.

Data Analysis

Mean baseline oxygen saturation values will be compared with the values obtained after application of the experimental device by Student's paired t test. Statistical significance will be accepted at the 95% confidence level ($p<0.05$).

Wilcoxon rank sum test will be used to compare comfort level assessment scores.

ETHICAL CONSIDERATIONS

Patients will be required to complete an informed consent prior to their participation in the study. The consent is included (appendix 3). Consent to photographs of notable ear abrasions for illustrative purposes for publication has also been included in the patient consent. Care will be taken to only show patient's ears. Patient identity will not be revealed.

SUPPLIES AND EQUIPMENT

The oxygen saturation monitor is being supplied by the FHH repiratory department for the duration of the study. The Comf0_2-strap was invented by Dr. Semeniuk and is being supplied courtesy of Limark Medical. The strap is standard green elastic composed with the exact material as existing oxygen mask straps (latex free, polyester, isopreme).

APPENDIX 2

UNIT MANAGER AND DEPARTMENT HEAD CONSENTS TO RECRUIT PATIENTS

Dr. Todd Anderson
Division of Cardiology
1403 - 29 Street NW, Calgary, Alberta
CANADA, T2N 2T9
Phone: (403) 670-1020 Fax: (403) 670-1592

UNIVERSITY OF CALGARY

RE: Consent to recruit patients from unit _____ for Comfo$_2$-strap™ clinical trial

Background: Existing oxygen mask straps secure the mask at an angle that results in ear abrasions and discomfort for the patient. Frequent readjustment of the mask and strap is essential to establish proper, comfortable mask placement and subsequent medical therapy. The Comfo$_2$-strap™ is angled so that a more secure position of the mask is obtained without contacting patient ears. Specific objectives of this controlled clinical trial are to assess device efficacy and patient comfort.

Methods: Patients receiving oxygen therapy by mask will be asked to sign an informed consent prior to participation in the study.
To test efficacy: Control oxygen levels will be monitored every 5 minutes for 30 minutes using a finger probe oxygen saturation measuring device to confirm stable oxygen saturation levels. The existing oxygen mask strap will be replaced with the control or experimental Comfo2-strap after ensuring the oxygen saturations decrease by 5%. Oxygen levels will be assessed every 5 minutes for another 30 minutes to confirm stable oxygen saturation levels using the experimental device.
To test patient comfort: Comfort level assessment will be in the form of a patient questionnaire to be completed before the experimental strap is trialed. This will assess comfort level of the existing oxygen mask strap. Patient's will be asked to answer the same questionnaire 24 hours after the existing strap is replaced with the experimental strap. Patients will be asked to continue the use of the experimental strap until oxygen therapy is discontinued as part of there regular medical treatment or until the 3 day end point of the study. This will allow nursing staff to comment on the security of mask position on a sheet of paper that will be left by the patient's bedside for the duration of the study. Notable ear abrasions will be photagraphed for illustrative purposes for publication.

Summary: The Comfo$_2$-strap™ may result in an improved quality of life for the patient if proven to be effective and comfortable.

Principle Investigator: Dr. T. Anderson M.D.
Other Investigator: Dr. L. Semeniuk PhD

My signature below acknowledges and accepts the impact (clinical, financial or otherwise) of this research study on my department/division/program/portfolio and I agree with the costs itemized in the study budget.

Unit Patient Care Manager: _____ _____ _____
Printed name Signature Date

Unit Medical Director: _____ _____ _____
Printed name Signature Date

Heart Health

CRHA

APPENDIX 3

PATIENT CONSENT

Dr. Todd Anderson
Division of Cardiology
1403 - 29 Street NW, Calgary, Alberta
CANADA, T2N 2T9
Phone: (403) 670-1020 Fax: (403) 670-1592

UNIVERSITY OF CALGARY

CONSENT

Institution: Foothills Hospital and the University of Calgary

Research Project Title: Efficacy and Comfort Assessment of the Comfo$_2$-strap

Principal Investigator: Dr. T. Anderson M.D.

Co-investigator: Dr. L.Semeniuk PhD

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

It is common for oxygen mask straps to consist of a single thin elastic band that fits around the patient's head with each end of the elastic securing each side of the medical mask. Devices of this type are, however, inefficient because the band secures the mask at an angle that results in ear abrasions and improper mask placement. Frequent readjustment of the mask and strap are essential to establish proper, comfortable mask placement and subsequent medical therapy. We have found that these disadvantages may be overcome by providing a strap that is angled so that contact with the ears no longer occurs thus eliminating ear abrasions. Ultimately, concurrent effective and comfortable placement of existing medical masks may be achieved with this strap that results in an improved quality of life for the patient.

The aims of this study are:

1. To study the effectiveness of the experimental strap in maintaining oxygen saturation.
2. To assess whether comfortable mask placement is achieved with the experimental strap.

This study may or may not be of personal benefit for you, but the information obtained by your participation may prove to be important in the treatment of patients using oxygen masks in the future.

Your participation in this study will not disrupt your regular care. You will be placed in either one of two groups. The first group will be a control group and the second, the study group. The existing mask strap will be replaced by a strap in both groups. You will not be told which strap you are receiving. In the control group, the existing oxygen mask strap will be replaced with an

identical strap. In the study group, the existing oxygen mask strap will be replaced with the study strap. Your oxygen saturation levels will be monitored using a finger probe every 5 minutes for 30 minutes before and after the experimental strap is put on, a total of 60 minutes. You will then be asked to complete a comfort level scale assessment that will assess your level of comfort with the existing mask strap and 24 hours after the experimental strap. You will be asked to continue the use of the experimental strap until oxygen therapy is discontinued as part of your regular medical treatment or until the study is over after 3 days. This will allow nursing staff to comment on the security of mask position on a sheet of paper that will be left by your bedside for the duration of the study. If you have ear abrasions from the existing oxygen mask straps, photographs of only the ear abrasions may be taken for illusrative purposes for publication. The choice of which group you will participate in will be random, and you will not be told which group you have been assigned to. This is called a randomized, blinded study which is an accepted way of doing research in an unbiased manner.

There are no known adverse effects associated with the use of the experimental strap. If any complications do occur, the professional and technical expertise is available to deal promptly with it.

All information obtained as part of this study will be confidential and only used for our research. Although unlikely, if new information regarding your condition is found, we will make this information available to your physician if it contributes to your care.

Your identity will be kept confidential, within limits of the law. Your participation is voluntary. You will not be paid for your participation as a subject.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health or care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

_____ Phone# _____

If you have any questions concerning your rights as a possible participant in this research, please contact the office of the Medical Bioethics, Faculty of Medicine, University of Calgary, at 220-7990.

Participant printed name	Signature	Date
Investigator printed name	Signature	Date
Witness printed name	Signature	Date

A copy of this consent form has been given to you.
Please keep it for you records and reference.

APPENDIX 4

SAMPLE COMFORT LEVEL ASSESSMENT SCALE

Figure 1. Sample Visual Analogue Scale

Reference

1. Wewers E, Lowe NK. A critical review of visual analogue scales in the measurement of clinical phenomena. Research in Nursing and Health. 1990; 13: 227-236.

2. Russell CJ, Bobko P. Moderated regression analysis and Likert Scales: Too course for comfort. Journal of Applied Psychology. 1992; 3: 336-342.

Exhibit C
of the Declaration under 37 CFR Section 1.132
by Lisa Semeniuk

FACULTY OF MEDICINE | UNIVERSITY OF CALGARY

Medicine, Faculty of Medicine
Foothills Hospital
University of Calgary
C210 1403 29th St. NW
Calgary, AB T2N 2T9

Phone: (403) 944-2510
Fax: (403)944-2876
Email: jennifer.macrae@calgaryhealthregion.ca

March 3, 2006

Dear Sir/Madam,

Medical care of my patients not only addresses pharmacologic therapy, but also takes into consideration their emotional, spiritual, and overall well-being. This becomes even more apparent for patients in advanced stages of disease. Patient comfort is a primary concern. It is to this end that I feel the importance of addressing a serious problem often encountered in the hospital setting with regards to my patients who often require oxygen supplementation. The ear abrasions resulting from this therapy adds considerable discomfort and added, unwanted burden to these patient already suffering from multiple end-organ damage.

I have seen this problem of ear abrasions for many years as a physician. The problem is not exclusive to this hospital. I have encountered it in every hospital that I have cared for patients.

The possibility of addressing this problem in a proactive rather than retroactive way is long-over due and a concept entirely analogous to a paradigm shift from secondary treatment to primary medical prevention. An important practice supported by all physicians.

The severity and extreme problem encountered as a result of current oxygen therapy, which uses a single elastic strap to hold the oxygen mask to a patient's face, is entirely preventable with the strap that Lisa Semeniuk has developed.

I intend to use Dr. Semeniuk's strap on all patients in my care who are receiving oxygen therapy, when the strap becomes commercially available. I have no doubt that other physicians will do the same, as it solves a real problem for which there is currently no practical solution.

Sincerely,

Dr. Jennifer MacRae MSc MD FRCPC

Exhibit D
of the Declaration under 37 CFR Section 1.132
by Lisa Semeniuk

March 13, 2006

calgary health region

Dear Sir or Madam,

I am a critical care supervisor in the Respiratory Services Department at the 800 bed Foothills Medical Centre in the Calgary Health Region. At any given time throughout the day, there are 20-30 patients on oxygen therapy by mask at our institution. Ear abrasions related to current straps and masks available are a regular occurrence and create a patient safety concern. The tissue breakdown seen from the current straps available on oxygen masks are at times quite deep and very painful for the patient.

The most difficult and often unappreciated pain comes from those individuals who have had strokes who either are unable to reach up and manipulate their mask or are unable to verbally communicate their pain. Unfortunately, these are the patients that often require long term oxygen by mask therapy due to neural complications that affect their achieving adequate oxygen levels.

We have seen first-hand during the clinical trial the benefits of the strap that has been created by Dr. Semeniuk. This product has provided more comfort as mentioned by patients, as well as shown very little skin break down. Perhaps an even greater advantage that we anticipate, that was not evaluated fully in the clinical trial, is the fact that it appears to keep the oxygen mask in the proper position on patients better than the current masks, especially in patients that are unable to adjust the oxygen mask after it slips down to their chin. This problem often occurs in comatose, confused, or sleeping patients.

There are currently no devices available that eliminate the occurrence of skin abrasions, generally. However, Dr. Semeniuk's strap appears to reduce the occurrence of skin abrasions, and avoids ear abrasion altogether, as it does not touch the ear. This device would be of benefit should it be available to hospitals to improve patient safety and comfort, and I for one would use it, should it become commercially available.

Sincerely,

Will Cunnington, RRT
Supervisor Heart Health/Regional NPT
Foothills Medical Centre
Calgary Health Region

Exhibit E
of the Declaration under 37 CFR Section 1.132
by Lisa Semeniuk

University Technologies International Inc.
A Company Wholly Owned by the University of Calgary

January 13, 2005

UTI Ref#: 683.1BV

Dr. Lisa Semeniuk
63 Sinclair Crescent SW
Calgary, AB T2W 0M1

Dear Lisa:

Re: ComfO$_2$ Strap

UTI has now completed its assessment of the *ComfO$_2$ Strap* for our ability to license the technology. Our evaluation covered such factors as the current state of development, type and quality of patent or other protection, scientific and technical merit of the invention, time and effort needed to commercialize, market potential, and nature and extent of competitive advantage.

We are impressed with the amount of time and resources you have already dedicated to this project. The fact that you filed for a patent early in the development of the invention is very positive.

The fact that you have a prototype and have done some initial testing which shows that the device does reduce ear abrasion discomfort is also very impressive.

Our biggest concern with this invention is the nature of the patent protection that can be obtained. There is significant prior art in the field and the first office action resulted in all claims being rejected on the basis that they were "anticipated" or "obvious". I have spoken to Susan Rancourt and understand that [redacted] This could result in the patent being allowed.

I understand Susan's strategy and am hopeful that it will have a positive result. However, it is a serious concern for UTI's ability to license the invention. Unless an invention has broad patent claims that will allow a licensee to exclude others from making and selling a similar invention, it is difficult to engage the interest of a company and to conclude an agreement with any significant financial value.

The result of our assessment is that we cannot see proceeding to act as your agent as this time. Should the patent process proceed positively, we would be happy to re-evaluate the opportunity at the time a notice of allowance is received from the patent office. At that time, we would review the claims once again to see if the invention meets our criteria.

.../

I'm sorry that we could not be of immediate assistance but look forward to future discussions.

Sincerely,

Hugh Jones
Vice President

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